

REMARKS

I. Overview

Applicants have reviewed and considered the Office Action dated March 14, 2006 and the references cited therewith. Applicants note that claims 2, 9, 18, 25, 32, 39, 46, and 53 are pending in the instant application. Applicants acknowledge Examiner's acceptance of the election of Group II, claims 2, 9, 18, 25, 32, 39, 46 and 53 with a species election of pig. Applicants acknowledge that claims 1, 3-8, 10-17, 19-24, 26-31, 33-38, 40-45, 47-52, and 54-58 are withdrawn from further consideration. Claims 9, 25, 39, and 53 have been cancelled. Applicants have amended claims 2, 18, 32, and 46 to recite "A method for determining robustness characterized by higher than average lifetime average daily gain among two or more pigs" to expedite prosecution. Support for these amendments may be found in the specification at Table 3 and paragraph 22. Applicants respectfully request reconsideration of the above-identified application in view of the amendments above and the remarks that follow.

II. Priority

The Examiner states that Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. That is the later-filed application must be an application for a patent for an invention which is also disclosed in the prior application.

The Examiner writes that the disclosure in the ADS of the prior-filed application, Application No. 60/370,725, fails to provide adequate support for enablement in the manner provided by the first paragraph of 35 U.S.C. § 112 for one or more claims of this application.

Applicants have amended the specification so that it now claims the benefit of priority to provisional application serial no. 60/390,725, filed June 21, 2002.

III. Specification

The Examiner writes the use of trademarks LSM® (p. 7, lines 26), Pfizerpen® G (p. 12, line 20), Garacin® (p.12, line 20), Suvaxyn® (p. 12, line 13), Respinfend® (p. 12, line 33), and Neo-Terramycin® (p. 14, line 14) has been noted in the application. The Examiner writes it should be capitalized wherever it appears and be accompanied by the generic terminology.

Accordingly, Applicants have capitalized the Trademarks LSM, Pfizerpen, Garacin, Suvaxyn, Respinfend and Neo-Terramycin as suggested by the Examiner and note that they have been amended to be accompanied by the appropriate generic terminology. Applicants have made every effort to prevent the use of trademarks in any manner which might adversely affect their validity as trademarks and request that this objection to the specification be withdrawn.

IV. Information Disclosure Statement

Applicants acknowledge the Examiner's statement that the listing of our references in the specification is not a proper information disclosure statement.

V. 35 U.S.C. § 112

Claims 2, 9, 18, 25, 32, 39, 46, and 53 stand rejected under 358, 25, 32, 39, 46, and 53 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method for measuring and predicting lifetime average daily gain (ADG) among two or more pigs comprising providing two or more pigs, determining in each pig the quantity of

CD16/CD2 double-staining positive antigen-expressing PBMC cells, determining a statistically significant association between a pig's quantity of CD16/CD2 double-staining antigen-expressing PBMC cells and ADG, allegedly does not reasonably provide enablement for above described method as a method for selecting for robustness or for the measurement of CD16/CD2 quantity in any cells and also does not enable the use of this method for selecting for the pig in order to improve robustness based on association.

Applicants respectfully traverse this rejection as the Office Action has failed to meet the initial burden of establishing an explanation to doubt the scope of enablement of the claimed invention. MPEP § 2164.04. The Examiner writes that furthermore, because of the breadth encompassed by selection and because no selection over progeny have been disclosed, an artisan would not know if the instant invention would truly work as a tool to select for superior, more robust pigs. The Examiner writes that an artisan would have to use the method over a long time period to determine if the method truly selected for robustness.

Applicants respectfully submit that the reasons identified in the Office Action do not provide an objective reason to doubt the truth of the statements in the specification as originally filed. Even if the specification does not disclose the actual selection of pigs for robustness based on the data for robustness selection, it is not synonymous with one skilled in the art being unable to do so. Applicants provide ample guidance and direct the Examiner's attention to Example 1, where Applicants show by example how to prepare isolate peripheral blood mononuclear cells (PBMCs) from blood and their use in flow cytometry assays. Applicants teach how to isolate PBMCs from the blood of a pig; incubate the PBMCs with a primary monoclonal antibody specific for CD2 and CD16; label the PBMCs with a secondary antibody conjugated to a fluorescent dye; count the PBMCs that express CD2 and CD16 using flow cytometry, and

calculate the percentage of PBMCs that express CD2 and CD16. Published Specification at Tables 1 and 3, paragraphs 28, 32-36, 55, 64, 70, 71 73, and 81. The specification describes immunostaining the isolated PBMCs and quantitating them using flow cytometry analysis. Data can be easily analyzed using software as described in the published specification at paragraph 81. The determination of whether there is a significant association between the amount of CD2/CD16 antigen expressing cells and robustness can be determined using statistical analysis. These techniques are routinely employed by one of skill in the art. Thus, one skilled in the art can use this data to identify and select for robust pigs for use in breeding or other production systems. The Examiner has failed to provide any reason to doubt that one of skill in the art would not be able to select a pig with robustness based on lifetime average daily gain (ADG), hot carcass measurements or feed conversion.

The Examiner writes that the term "selection" in the livestock production art and "robustness" encompasses broader meanings than implied by the specification. The Examiner writes that the specification only provides support for lifetime ADG and its association with CD2/CD16 positive PBMC cells and not the robustness. While Applicants do not agree with the bases for rejection, Applicants have amended claims 2, 18, 32, and 46 to recite "A method for determining robustness characterized by higher than average lifetime average daily gain among two or more pigs" to expedite prosecution. Support for these amendments may be found in the published specification at Table 3 and paragraph 22. In light of the above, Applicants respectfully request that this rejection to claims 2, 9, 18, 25, 32, 39, 46, and 53 be withdrawn and reconsidered.

VI. 35 U.S.C. § 112 - Indefiniteness

Claims 2, 9, 18, 25, 32, 39, 46, and 53 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which application regards as the invention.

The Examiner writes the instant claims recite, "selecting" or "selection". The Examiner writes the metes and bounds of this term is unclear by its uses in the claims and specification. The Examiner writes selection may be defined as sorting in the instant invention or could have broader implications in driving a genetic change for improvement of livestock product.

While not acquiescing to the Examiner's reason for the rejection, the Applicants have amended 2, 9, 18, 25, 32, 39, 46, and 53 to remove the phrase "selecting for" and replaced it with the word "determining" to expedite prosecution. In light of the above, Applicants respectfully request that this rejection to claims 2, 9, 18, 25, 32, 39, 46, and 53 be withdrawn and reconsidered.

VII. Conclusion

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, reading "Janaé E. Lehman Bell". The signature is fluid and cursive, with the first name "Janaé" being the most prominent part.

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